

CLAIMS:

1. A method for monitoring the quality of a herbal medicine comprising the steps of:
  - (a) providing a first sample of the herbal medicine;
  - 5 (b) extracting the sample with a polar solvent to produce a polar extract and a non-polar residue;
  - (c) characterizing the polar extract.
- 10 2. The method of claim 1 wherein the polar extract is fractionated prior to characterization.
3. The method of claim 2 wherein the polar extract is fractionated by:
  - (a) ion-exchange chromatography to produce an extract enriched in ionic-compounds and a non-ionic residue; and then
  - 15 (d) chromatographically fractionating the enriched extract of step (a) to yield one or more polar fractions comprising one or more ionic phytochemical(s).
4. The method of claim 3 wherein the chromatographic fractionation comprises gas-liquid chromatography (GC).
- 20 5. The method of claim 4 wherein the enriched extract is derivitized prior to gas-liquid chromatography.
6. The method of any one of claims 3 to 5 further comprising the steps of: (i) scavenging  
25 the non-ionic residue for non-ionic species by subjecting the non-ionic residue to hydrophobic interaction or reversed-phase chromatography to produce a scavenged non-ionic extract depleted in sugars; and (ii) characterizing the scavenged extract.
7. The method of claim 6 wherein the scavenged extract is fractionated prior to  
30 characterization.
8. The process of claim 7 wherein the scavenged extract is fractionated by chromatographic fractionation to yield one or more scavenged fractions comprising one or more non-ionic phytochemical(s).
- 35 9. The method of claim 8 wherein the chromatographic fractionation comprises high performance liquid chromatography (HPLC).

10. The method of any one of the preceding claims further comprising: (i) extracting a second sample of the herbal medicine or sequentially extracting the non-polar residue of the first sample with a non-polar solvent to produce a non-polar extract; and (ii)  
5 characterizing the non-polar extract.
11. The method of claim 10 wherein the non-polar extract is fractionated prior to characterization.
- 10 12. The method of claim 11 wherein the non-polar extract is fractionated by: (i) subjecting the non-polar extract to hydrophobic interaction or reversed-phase chromatography to produce an extract depleted in fats and chlorophyll; and (ii) chromatographically fractionating the depleted extract to yield one or more non-polar fractions comprising one or more non-polar phytochemical(s).  
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13. The method of claim 12 wherein the chromatographic fractionation comprises high performance liquid chromatography (HPLC) and/or gas-liquid chromatography (GC).
14. The method of any one of the preceding claims wherein the polar and/or non-polar  
20 extracts are characterized:  
    (a) functionally; and/or  
    (b) physically; and/or  
    (c) chemically.
- 25 15. The method of claim 14 (a) wherein the functional characterization comprises a biological assay, for example selected from:  
    (a) *in vivo* or *in vitro* assays; and/or  
    (b) enzyme inhibition assays (for example glycosidase and/or lipase inhibition);  
        and/or  
30      (c) receptor binding assays; and/or  
    (d) cellular assays (e.g. cell replication, cell-pathogen, cell-cell interaction and cell secretion assays); and/or  
    (e) immunoassays; and/or  
    (f) anti-microbial activity (e.g. bacterial and viral cell-binding and/or replication)  
35      assays; and/or  
    (g) toxicity assays (e.g. LD<sub>50</sub> assays).

16. The method of claim 14 (b) wherein the physical characterization is selected from:
- (a) quantification of the phytochemical component(s); and/or
  - (b) measurement of the purity of the constituents; and/or
  - (c) determination of molecular weight (or molecular weight distribution or  
5 various statistical functions thereof in the case of fractions which comprise a  
plurality of different phytochemical constituents); and/or
  - (d) determination of the molecular formula(e) (e.g. by nuclear magnetic  
resonance); and/or
  - (e) spectral analysis.
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17. The method of claim 16 (e) wherein the spectral analysis produces:
- (e) mass spectra (e.g. the mass to charge (m/z) value versus abundance), and/or
  - (f) chromatographic data (e.g. spectra, column retention times, elution profiles  
etc), and/or
  - 15 (g) photodiode array (PDA) spectra (e.g. in both UV and visible ranges), and/or
  - (h) nuclear magnetic resonance (NMR) spectra (e.g. spectral data sets obtained  
via  $^1\text{H}$  and/or  $^{13}\text{C}$  NMR).
18. The method of claim 16 or claim 17 wherein spectral analysis is coupled with  
20 fractionation of the extract, for example by use of GC-MS and/or HPLC-PDA-MS.
19. The method of claim 14 (c) wherein the chemical characterization measurements of:
- (a) the chemical reactivity of phytochemical constituent(s); and/or
  - (b) the solubility of phytochemical constituent(s); and/or
  - 25 (c) the stability and melting point of phytochemical constituent(s).
20. The method of any one of claims 2 to 19 wherein the fractionation of the extract  
yields a defined fraction or an isolated (e.g. substantially pure) phytochemical.
- 30 21. The method of any one of the preceding claims wherein the characterization yields a  
phytochemical profile.
22. The method of claim 21 further comprising the step of analysing the phytochemical  
profile to determine whether one or more bioactive principle(s) are present in the  
35 sample(s).

23. The method of claim 21 or claim 22 further comprising the step of analysing the phytochemical profile to determine whether one or more bioactive marker(s) are present in the sample(s).
- 5 24. The method of any one of claims 21 to 23 further comprising the step of analysing the phytochemical profile to determine whether it meets a standard specification.
25. A method for identifying a bioactive principle in a herbal medicament, the method comprising the steps as defined in any one of claims 1 to 20.
- 10 26. The method of claim 25 wherein the sample is a blood sample which is obtained by administering a sample of the herbal medicine to a subject and then extracting a blood sample from the subject.
- 15 27. A process for producing a herbal medicine comprising the step of monitoring the quality of the herbal medicine by a method as defined in any one of the claims 1 to 24.
28. A herbal medicine obtainable by the process of claim 27.